THE WEINBERG GROUP INC.

1220 Nineteenth St, NW, Suite 300
Washington, DC 20036-2400
Phone 202.833.8077
Fax 202 833.7057
e-mail science@weinberggroup.com

WASHINGTON
NEW YORK
SAN FRANCISCO
BRUSSELS
PARIS

August 8, 2002

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

OVERNIGHT COURIER 8/8/02

SUITABILITY PETITION

This petition is submitted pursuant to 21 CFR §10.20 and §10.30, as provided for in 21 CFR §314.93, and Section 505(j)(2)(c) of the Federal Food, Drug, and Cosmetic Act, to request the Commissioner of the Food and Drug Administration to declare that the drug product Amoxicillin Tablets for Oral Suspension 300 mg and 600 mg are suitable for submission as an abbreviated new drug application (ANDA).

A. **Action Requested**

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Amoxicillin Tablets for Oral Suspension 300 mg and 600 mg are suitable for submission as an ANDA. The reference listed drug product upon which this petition is based is Amoxil® (amoxicillin) for Oral Suspension, available in strengths of 200 mg/ 5 mL and 400 mg/5 mL. Amoxil® has been approved as safe and effective by the FDA. The petitioner seeks a change to include these additional strengths.

The proposed drug products are expected to demonstrate bioequivalence to Amoxil® for Oral Suspension 400mg/5mL; data will be submitted at a later date.

B. **Statement of Grounds**

Amoxicillin Tablets for Oral Suspension are presented for administration by dispersing a single tablet in a specified amount of water.

02P-0358

CP1

As the amoxicillin dosage regimen varies between 250 mg to 3 g/day depending on the type of infection, the inclusion of the additional 300 mg and 600 mg strengths of Tablets for Oral Suspension would give flexibility to the physician to prescribe these new strengths depending on the body weight of the patient. Neither the 300 mg nor the 600 mg dosage strength is available for the currently marketed Amoxicillin (Amoxil®) formulations.

Additionally, this dosage form offers a better alternative to the powder for oral suspension due to the following advantages:

- Unit dose dispensing
- Convenience to the patient with respect to the ease of administration even while traveling
- Storage of the product will not require special conditions, such as refrigeration
- Better precision of dosage over the traditional teaspoonful
- Ease of carrying

The requested change in strength should not raise any questions regarding safety or efficacy as the proposed strengths represent intermediate strengths between the already approved lowest (125 mg/5 mL) and highest (875 mg) strengths of Amoxicillin formulations. Moreover, these proposed strengths represent strengths already prescribed for use in an identifiable patient population (i.e., children, whose doses are prescribed on a mg/kg basis as described in the labeling for the reference listed drug).

Labeling of the proposed product (provided in Attachment 1) will be the same as that of the reference listed drug product (provided in Attachment 2), with the exception of the introduction of the 300 mg and 600 mg strengths of Tablets for Oral Suspension in the "Description" and "How supplied" sections of the labeling. The dosing recommendations will remain unaltered as the labeling already provides for utilization of the 300 mg and 600 mg strengths within the mg/kg dose recommendations.

C. **Pediatric Use Information**

As the package insert of GlaxoSmithKline's Amoxil® contains adequate dosing and administration information for the pediatric population, no additional studies are required.

D. **Environmental Impact**

An environmental assessment report on the action requested in this petition is not required under 21 CFR 25.31.

E. **Economic Impact**

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the Agency.

F. **Certification**

The undersigned certifies that to the best of his knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

Nicholas M. Fleischer, R.Ph., Ph.D.
Director of Biopharmaceutics
THE WEINBERG GROUP INC.

NMF/kh

Enclosure

cc Gary Buehler, Director, Office of Generic Drugs